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DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION, CONTACT: Information on licensing, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Improved Fixative for Paraffin-Embedded Tissue Samples

Description of Technology:

Tissues samples collected during medical procedures, such as biopsies, are used to diagnose a wide variety of diseases. Before diagnosis, patient samples are typically processed by fixation and paraffin embedding. This fixation/embedding process is used to preserve tissue morphology and histology for subsequent evaluation. Unfortunately, most fixative agents damage or destroy nucleic acids (RNA and DNA) and proteins, thereby potentially impairing diagnostic assessment of tissue.

Researchers in the National Cancer Institute's Laboratory of Pathology have developed an improved tissue fixative solution that is formaldehyde-free. This fixative, BE70, significantly improves DNA, RNA, and protein biomolecule integrity in histological samples compared to traditional fixatives. Additionally, BE70 is compatible with current protocols and does not alter tissue processing. *In vitro an in vivo* data are available and the fixative has been tested on paraffin-embedded samples

Potential Commercial Applications:

- Improves integrity of fixed tissue samples
- Improves RNA/DNA quality in fixed tissue samples
- Non-cross linking, improves protein quality

Value Proposition:

- There is substantial interest in new fixatives to replace neutral buffered formalin (a carcinogen) as primary fixative agent for surgical pathology
- BE70 overcomes several limitations of other fixatives, including cost and disposal issues
- Could be formulated as a concentrate, and marketed as an additive (to be added during dilution of ethanol)

Development Stage:

In vivo data: YES

Inventor(s):

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Intellectual Property:

HHS Reference No. E-139-2015/0-US-01

US Provisional Patent Application 62/255,030 (HHS Reference No. E-139-2015/0-US-01) filed November 13, 2015, entitled “Fixative and Methods of Use”.

Publications:

Perry C, Chung JY, et al. *J Histochem Cytochem*. 2016 May 24;E-pub [PMID: 27221702]

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: June 28, 2016.

John D. Hewes

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